510(K) SUMMARY

Addition of 3D Measurements to SONOLINE® Elegra Diagnostic Ultrasound system

This summary of safety and effectiveness is provided as part of this Premarket Notification in compliance with the Safe Medical Device Act of 1990 revisions to 21 CFR, Part 807.92, Content and Format of a 510(k) Summary.

1. **Submitted By:**
Siemens Medical Systems, Inc., Ultrasound Group
22010 S.E. 51st Street
Issaquah, WA 98029

Contact Person:
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Regulatory Affairs

Phone: (425) 557-1229
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Date Prepared:
September 11, 2000

2. **Proprietary Name:**
SONOLINE Elegra Advanced
SONOLINE Elegra

Common/ Usual Name:
Diagnostic Ultrasound System with Accessories

Classification Name:
Ultrasonic Pulsed Doppler Imaging System (Product Code 90 IYN, 21 CFR 892.1550)

3. **Predicate Device:**
K945072, 11/21/95, cleared as the Q4000, marketed as the SONOLINE Elegra Advanced
K950157, 4/5/96, cleared as Q64XX, marketed as the SONOLINE Elegra
K961833, 10/29/96, SieScape panoramic display for SONOLINE Elegra Advanced
K981626, 5/27/98, 3D Imaging for SONOLINE Elegra platform
K981528, 10/28/98, Tissue Harmonic Imaging for SONOLINE Elegra platform
K993517, 11/02/99, Medison America, Inc., Combison 530D/Voluson 530D

4. **Device Description:**
The SONOLINE Elegra is a general purpose, mobile, software-controlled, diagnostic ultrasound system with an on-screen display for thermal and mechanical indices related to potential bioeffect mechanisms. Its function is to acquire ultrasound data and display it in B-Mode, M-Mode, Color Mode, Pulsed (PW) Doppler Mode, Continuous (CW) Doppler Mode, or in a combination of modes, on a CRT display.

The SONOLINE Elegra, has been designed to meet the following product safety standards:

- UL 2601, Safety Requirements for Medical Equipment
- CSA 22.2 No. 601-1, Safety Requirements for Medical Equipment
- Standard for Real Time Display of Thermal and Mechanical Indices on Diagnostic Ultrasound Equipment, AIUM/NEMA, 1992.
- 93/42/EEC Medical Devices Directive

- EN60601 = (IEC 601-1-1 + IEC 601-1-2), Safety and EMC Requirements for Medical Equipment

5. Intended Uses:

The SONOLINE Elegra ultrasound imaging system is intended for the following applications: General Radiology, Abdominal, Intraoperative, Small Parts, Transcranial, OB/GYN, Pelvic, Neonatal/Adult Cephalic, Urology, Vascular, Musculoskeletal, Superficial Musculoskeletal, and Peripheral Vascular applications.

The system also provides for the measurement of anatomical structures and for analysis packages that provide information that is used for clinical diagnosis purposes.

6. Technological Comparison to Predicate Device:

SONOLINE Elegra with 3D Imaging is a previously cleared device (K981626, 5/27/98). The purpose of this submission is to receive clearance for the addition of measurement capability on 3 dimensional images.

Comparison to Medison: The SONOLINE Elegra and Medison 530D MT are substantially equivalent in that they both produce 3D volume data sets and provide measurement capability utilizing a software algorithm providing the assisted detection of structure contours and volume calculations.

End of 510(k) Summary

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 0 2000

Siemens Medical System, Inc.
C/o Mark Job
TUV Product Service Inc.
1775 Old Highway 8 NW, Suite 104
New Brighton, MN 55112-1891

Re: K003125
Sonoline Elegra Diagnostic Ultrasound System
Dated: October 4, 2000
Received: October 5, 2000
Regulatory class: II
21 CFR 892.1550/Procode: 90 IYN
21 CFR 892.1560/Procode: 90 IYO
21 CFR 892.1570/Procode: 90 ITX

Dear Mr. Job:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known): K003125

Device Name: SONOLINE® Elegra platform of Diagnostic Ultrasound Systems

Indications for Use:

The SONOLINE Elegra platform of ultrasound imaging systems are intended for the following applications: General Radiology, Abdominal, Intraoperative, Small Parts, Transcranial, OB/GYN, Pelvic, Neonatal/Adult Cephalic, Urology, Vascular, Musculoskeletal, Superficial Musculoskeletal, and Peripheral Vascular applications.

The systems also provide for the measurement of anatomical structures and for analysis packages that provide information used for clinical diagnosis purposes.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X (Per 21 CFR 801.109) OR Over-the-Counter-Use ____ (Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K003125